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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/576,290	05/23/2000	Shuji Hinuma	47176-DIV(342)	4462

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EXAMINER

ROMEO, DAVID S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 12/12/2001

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/576,290

Applicant(s)

HINUMA ET AL.

Examiner

David S Romeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/776,971.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Claims 21-27 are pending.

2. Applicant's election of the species polypeptide, SEQ ID NO: 64, and ^{125}I in Paper No. 11 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 21-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) to the extent that they are drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 21, 22, 24, 25-27 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are directed to a labeled and/or amidated polypeptide. Radioisotopes, generally, and ^{14}C , particularly, are labeling compounds, occur in

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nature, and are incorporated into proteins. C-terminal amidation is a naturally occurring modification of peptides. The claims read upon a labeled and/or amidated polypeptide as it occurs in nature. It is suggested that the claims be limited to a isolated polypeptide which is labeled.

5 Ferry (a12)¹ teaches that ¹⁴C is a carbon isotope that occurs naturally in living matter (column 1, full paragraph 2).

Henriksen teaches that peptide hormones often terminate in carboxamido groups, which are essential for full biologic activity (page 1876, full paragraph 1).

Claim Objections

10 6. Claim 26 is objected to because of the following informalities: The closing ")" should be "]"". Appropriate correction is required.

Double Patenting

15 7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

¹Citations by the examiner are in an alphanumeric format, such as "(a1)", wherein the "a" refers to the reference cited on the Notice of References Cited, PTO-892, and the "1" refers to the Paper No. to which the Notice of References Cited, PTO-892, is attached.

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Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

5 A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10 8. Claims 21-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 9 of U.S. Patent No. 6,228,984 in view of Galli (b12), Schwartz (c12), Henriksen (u12), and Whitcomb (v12).

The claims of the patent are directed to or encompass a polypeptide comprising the amino acid sequence of SEQ ID NO: 73, and covers the instant application claims since the patent claims
15 have "comprising" language that does not exclude labeling and/or C-terminus amidation.

The polypeptides of the present invention are ligands G protein coupled receptor proteins.

Galli teaches that the analysis of G protein coupled receptor proteins requires the availability of ligands with relatively high affinity constants, because only these will be capable of forming complexes with a long enough average life for withstanding the several necessary washes.
20 A wide range of radioiodine-labeled ligands have become available recently (column 4, lines 30-36).

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Schwartz teaches the radio-iodination of ligand polypeptides with ^{125}I (column 4, full paragraph 1).

It would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to label the polypeptides of the claims of the patent with ^{125}I with a reasonable expectation of success. One of ordinary skill in the art would be motivated to label the polypeptides of the claims of the patent with ^{125}I in order to analyze their receptor binding.

Henriksen teaches that peptide hormones often terminate in carboxamido groups, which are essential for full biologic activity (page 1876, full paragraph 1).

Whitcomb teaches an in vivo radioreceptor assay for polypeptide hormones for the identification of tissue hormone receptors (Abstract, section "Experimental Procedures" bridging pages E561-E562).

It would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to amidate the C-terminus of the polypeptides of the claims of the patent with a reasonable expectation of success. One of ordinary skill in the art would be motivated to amidate the C-terminus of the polypeptides of the claims of the patent because peptide hormones often terminate in carboxamido groups, which are essential for full biologic activity. Insofar as biologic activity of peptide hormones is a manifestation of receptor binding it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to amidate the C-terminus of the polypeptides of the claims of the patent and label the polypeptides of the claims of the patent

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with ^{125}I with a reasonable expectation of success. One of ordinary skill in the art would be motivated to make this modification in order to identify tissue receptors of the polypeptides of the claims of the patent. One of ordinary skill in the art would be motivated to make a pharmaceutical composition comprising the labeled/amidated polypeptides of the claims of the patent for use in the in vivo radioreceptor assay of Whitcomb.

Formal Matters

9. The application is not fully in compliance with the sequence rules, 37 C.F.R. § 1.821-1.825. Specifically, the specification fails to recite the appropriate sequence identifiers at each place where a sequence is discussed. See, for example, Figure 1. This is not meant to be an exhaustive list of places where the specification fails to comply with the sequence rules. The specification has not been checked to the extent necessary to determine the presence of all possible errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. *The application cannot issue until it is in compliance.* Nucleic acid sequences with 10 or more nucleotides, at least 4 of which are specifically defined, must comply with the sequence rules. Amino acid sequences with 4 or more residues, at least 4 of which are specifically defined, must comply with the sequence rules. Sequence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as "residues 14 to 243 of SEQ ID NO:23" is permissible and the fragment

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need not be separately presented in the "Sequence Listing." Applicant may bring the figure(s) into compliance by amending either the figure(s) or the "Brief Description of the Drawings" to recite the appropriate sequence identifier.

Correction is required.

- 5 If the corrections are extensive and/or could lead to confusion and mistake during the issue and printing processes, the specification may be required to be rewritten before passing the case to issue.

Conclusion

10. No claims are allowable.

10 ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

15 OFFICIAL PAPERS FILED BY FAX SHOULD BE DIRECTED TO (703) 308-4242.

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.



DAVID ROMEO
PRIMARY EXAMINER
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DECEMBER 10, 2001